4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 030

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 030" (Recognition List Number: 030), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 030" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149. Submit written comments concerning this document, or

recommendations for additional standards for recognition, to the contact person (see FOR FURTHER INFORMATION CONTACT). Submit electronic comments by email: standards@cdrh.fda.gov. This document may also be accessed on FDA's Internet site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 030 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT:

Scott A. Colburn,

Center for Devices and Radiological Health,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 66, rm. 3632,

Silver Spring, MD 20993,

301-796-6287.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the Federal Register of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus

Standards." The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the Federal Register, are identified in table 1 of this document.

Table 1.--Previous Publications of Standard Recognition Lists

February 25, 1998 (63 FR 9561).	November 3, 2006 (71 FR 64718).
October 16, 1998 (63 FR 55617).	May 21, 2007 (72 FR 28500).
July 12, 1999 (64 FR 37546).	September 12, 2007 (72 FR 52142).
November 15, 2000 (65 FR 69022).	December 19, 2007 (72 FR 71924).
May 7, 2001 (66 FR 23032).	September 9, 2008 (73 FR 52358).
January 14, 2002 (67 FR 1774).	March, 18, 2009 (74 FR 11586).
October 2, 2002 (67 FR 61893).	September 8, 2009 (74 FR 46203).
April 28, 2003 (68 FR 22391).	May 5, 2010 (75 FR 24711).
March 8, 2004 (69 FR 10712).	June 10, 2010 (75 FR 32943).
June 18, 2004 (69 FR 34176).	October 4, 2010 (75 FR 61148).
October 4, 2004 (69 FR 59240).	March 14, 2011 (76 FR 13631).
May 27, 2005 (70 FR 30756).	August 2, 2011 (76 FR 46300).
November 8, 2005 (70 FR 67713).	March 16, 2012 (77 FR 15765).
March 31, 2006 (71 FR 16313).	August 20, 2012 (77 FR 50114).
June 23, 2006 (71 FR 36121).	

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains "hypertext markup language (HTML)" and "portable document format (PDF)" versions of the list of "FDA Recognized Consensus Standards." Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 030

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA

Recognized Consensus Standards in the Agency's searchable database. FDA will use the term "Recognition List Number: 030" to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Biocompatibility			
2-156		AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process.	Extent of recognition.
2-178	2-191	ISO 10993-12 Fourth edition 2012-07-01 Biological evaluation of medical devices--Part 12: Sample preparation and reference materials.	Withdrawn and replaced with newer version.
2-184	2-192	USP 35-NF30:2012<87> Biological Reactivity Test, In Vitro--Direct Contact Test.	Withdrawn and replaced with newer version.
2-185	2-193	USP 35-NF30:2012 Biological Tests <87> Biological Reactivity Test, In Vitro--Elution Test.	Withdrawn and replaced with newer version.
2-186	2-194	USP 35-NF30:2012 Biological Tests <88> Biological Reactivity Tests, In Vivo, Procedure Preparation of Sample.	Withdrawn and replaced with newer version.
2-187	2-195	USP 35-NF30:2012 Biological Tests <88> Biological Reactivity Test, In Vitro, Classification of Plastics--Intracutaneous Test.	Withdrawn and replaced with newer version.
2-188	2-196	USP 35-NF30:2012 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics--Systemic Injection Test.	Withdrawn and replaced with newer version.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
B. Cardiovascular			
3-30	3-105	IEC 60601-2-25 Edition 2.0 2011-10 Medical electrical equipment--Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	Withdrawn and replaced with newer version.
3-61		IEC 60601-2-27 Edition 3.0 2011-03 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Withdrawn, see 3-95.
3-101		ANSI/AAMI/ISO 60601-2-27 Edition 3.0 2011-03 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Withdrawn, see 3-100.
3-59		ISO 5841-3 Second edition 2000-10-15 Implants for surgery--Cardiac pacemakers--Part 3: Low-profile connectors [IS-1] for implantable pacemakers.	Title, processes impacted, related CFR citation(s) and procode(s), and relevant guidance.
C. Dental/ENT			
4-43		ADA/ANSI Specification No. 5, Dental Casting Alloys: 1997.	Withdrawn, see 4-146.
4-87	4-196	ANSI/ADA Specification No. 69, 2010 Dental Ceramic.	Withdrawn and replaced with newer version.
4-94		Specification No.14, Dental Base Metal Casting Alloys: 1982 (Reaffirmed 1998).	Withdrawn, see 4-146.
4-96		ANSI/ADA Specification No. 30, Reaffirmed by ANSI October 2010 Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements.	Reaffirmation.
4-110		ADA/ANSI ADA Specification No. 11, Agar Impression Materials: 1997.	Withdrawn.
4-113		ADA/ANSI ADA Specification No. 20, Dental Duplicating Material; 1972 (Reaffirmed 1995).	Withdrawn.
4-131	4-198	ISO 3107 Fourth edition 2011-03 Dentistry--Zinc oxide/ Eugenol cements and zinc oxide/non-eugenol cements.	Withdrawn and replaced with newer version.
4-133	4-199	ISO 6876 Third edition 2012-06-01 Dentistry--Root canal sealing materials.	Withdrawn and replaced with newer version.
4-147		ADA/ANSI Specification No. 27, Resin-Based Filling Materials: 2005.	Withdrawn.
4-152	4-201	ISO 9693 Second edition 1999-12-15 Metal-ceramic dental restorative systems.	Withdrawn and replaced with newer version.
4-158		ISO 10139-1:2005, Dentistry--Soft lining materials for removable dentures--Part 1: Materials for short-term use Technical Corrigendum 1:2006.	Withdrawn--Duplicate, see 4-189.
4-192	4-202	ANSI/ADA Specification No. 58, 2010 Root Canal Files, Type H (Hedstrom).	Withdrawn and replaced with newer version.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
D. General			
5-56		ISO 15223-2 First edition 2010-01-15 Medical devices--Symbols to be used with medical devices labels, labelling, and information to be supplied--Part 2: Symbol development, selection and validation.	Withdrawn.
5-68		AAMI/ANSI/ISO 15223-2, Medical devices--Symbols to be used with medical device labels, labellings, and information to be supplied--Part 2: Symbol development, selection and validation.	Withdrawn.
5-72	5-73	ISO 15223-1 Second Edition 2012-07-01 Medical devices--Symbols to be used with medical device labels, labelling and information to be supplied--Part 1: General requirements.	Withdrawn and replaced with new version.
E. General Hospital/General Plastic Surgery			
6-13		ISO 595-1 First edition 1986-12-15 Reusable all-glass or metal-and-glass syringes for medical use--Part 1: Dimensions.	Contact person and title.
6-14		ISO 595-2 First edition 1987-12-15 Reusable all-glass or metal-and-glass syringes for medical use--Part 2: Design, performance requirements and tests.	Contact person.
6-15		ISO 7864 Third edition 1993-05-15 Sterile hypodermic needles for single use.	Contact person.
6-107		ASTM F 882-84 (Reapproved 2002) Standard Performance and Safety Specification for Cryosurgical Medical Instruments.	Withdrawn.
6-122		ISO 8536-5 Second edition 2004-02-01 Infusion equipment for medical use--Part 5: Burette infusion sets for single use, gravity feed.	Contact person.
6-148		ISO 7886-3 First edition 2005-03-01 Sterile hypodermic syringes for single use--Part 3: Auto-disable syringes for fixed-dose immunization.	Contact person.
6-170		ISO 7886-1 First edition 1993-10-01 Sterile hypodermic syringes for single use--Part 1: Syringes for manual use.	Contact person and title.
6-203	6-282	ASTM D6499-12 Standard Test Method for The Immunological Measurement of Antigenic Protein in Natural Rubber and its Products.	Withdrawn and replaced with newer version.
6-204		ISO 8537 Second edition 2007-10-01 Sterile single-use syringes, with or without needle, for insulin.	Contact person.
6-255	6-283	USP 35-NF30:2012 Sodium Chloride Irrigation.	Withdrawn and replaced with newer version.
6-256	6-284	USP 35-NF30:2012 Sodium Chloride Injection.	Withdrawn and replaced with newer version.
6-257	6-285	USP 35-NF30:2012 Nonabsorbable Surgical Suture.	Withdrawn and replaced with newer version.
6-258	6-286	USP 35-NF30:2012 <881> Tensile Strength.	Withdrawn and replaced with newer version.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-259	6-287	USP 35-NF30:2012 <861> Sutures-Diameter.	Withdrawn and replaced with newer version.
6-260	6-288	USP 35-NF30:2012 <871> Sutures-Needle Attachment.	Withdrawn and replaced with newer version.
6-261	6-289	USP 35-NF30:2012 Sterile Water for Irrigation.	Withdrawn and replaced with newer version.
6-262	6-290	USP 35-NF30:2012 Heparin Lock Flush Solution.	Withdrawn and replaced with newer version.
6-623	6-291	USP 35-NF30:2012 Absorbable Surgical Suture.	Withdrawn and replaced with newer version.
F. In Vitro Diagnostics			
7-7		CLSI/NCCLS LA1-A2 1994 Assessing the Quality of Radioimmunoassay Systems--Second Edition; Approved Guideline.	Withdrawn.
7-124		CLSI/NCCLS I/LA24-A Fluorescence Calibration and Quantitative Measurement of Fluorescence Intensity; Approved Guideline.	Withdrawn.
7-99	7-232	CLSI MM05-A2 Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline--Second Edition.	Withdrawn and replaced with newer version.
7-194	7-233	CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline--Second Edition.	Withdrawn and replaced with newer version.
G. Materials			
8-117	8-228	ASTM F86-12 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	Withdrawn and replaced with a newer version.
8-124		ASTM F2052-06e1 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	Relevant guidance.
8-128		ASTM F2213-06 (Reapproved 2011) Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.	Relevant guidance.
8-153		ASTM F2119-07 Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.	Relevant guidance.
8-176		ASTM F2503-08 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Relevant guidance.
8-227		ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging.	Relevant guidance .
8-137	8-229	ASTM F75-12 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Withdrawn and replaced with a newer version.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
8-142	8-330	ASTM F1978-12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser.	Withdrawn and replaced with a newer version.
8-155	8-331	ASTM F1580-12 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Withdrawn and replaced with a newer version.
8-209	8-332	ASTM F899-12 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with a newer version.
H. OB-GYN/Gastroenterology			
9-21		IS0 8600-4 First edition 1997-07-01 Optics and optical instruments--Medical endoscopes and certain accessories--Part 4: Determination of maximum width of insertion portion.	Contact person.
9-34		ISO 4074 First edition 2002-02-15 Corrected version 2002-12-01 Natural latex rubber condoms--Requirements and test methods.	Contact person.
9-36		ISO 8009 First edition 2004-10-01 Mechanical contraceptives--Reusable natural and silicone rubber contraceptive diaphragms--Requirements and tests.	Contact person.
9-37		ISO 8600-1 Second edition 2005-05-01 Optics and photonics --Medical endoscopes and endotherapy devices--Part 1: General requirements.	Contact person.
9-39		ISO 8600-5 First edition 2005-03-15 Optics and photonics--Medical endoscopes and endotherapy devices--Part 5: Determination of optical resolution of rigid endoscopes with optics.	Contact person.
9-40		ISO 8600-6 First edition 2005-03-15 Optics and photonics --Medical endoscopes and endotherapy devices--Part 6: Vocabulary.	Contact person.
9-43		ISO 16038 First edition 2005-11-01 Rubber condoms--Guidance on the use of ISO 4074 in the quality management of natural rubber latex condoms.	Contact person.
9-56		ASTM D 3492-08 Standard Specification for Rubber Contraceptives (Male Condoms).	Contact person.
9-61		IEC 60601-2-18 Edition 3.0 2009-08 Medical electrical equipment--Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Contact person.
9-58		ASTM D6324-08 Standard Test Methods for Male Condoms Made from Polyurethane.	Withdrawn.
I. Ophthalmic			
10-56		ANSI Z80.12-2007 (R2012) American National Standard for Ophthalmics--Multifocal Intraocular Lenses.	Reaffirmation.
10-57		ANSI Z80.13-2007 (R2012) American National Standard for Ophthalmics--Phakic Intraocular Lenses.	Reaffirmation.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
J. Orthopedics			
11-203		ASTM F1541-02 (Reapproved 2011)$^{\epsilon}$1 Standard Specification and Test Methods for External Skeletal Fixation Devices.	Title.
11-216		ASTM F1264-03 (Reapproved 2012) Standard Specification and Test Methods for Intramedullary Fixation Devices.	Reaffirmation.
11-229	11-244	ASTM F2083-11 Standard Specification for Total Knee Prosthesis.	Withdrawn and replaced with newer version.
11-233	11-245	ASTM F384-12 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.	Withdrawn and replaced with newer version.
11-236	11-246	ASTM F1717-12 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
K. Sterility			
14-64		ASTM F1929-98 (Reapproved 2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.	Relevant guidance.
14-169		ASTM F2391-05 (Reapproved 2011) Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas.	Relevant guidance.
14-197		ASTM F1608-00 (Reapproved 2009) Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method).	Relevant guidance.
14-211	14-362	AOAC 6.2.01:2012 Official Method 955.14 Testing Disinfectants against Salmonella enterica, Use-Dilution Method.	Withdrawn and replaced with newer version.
14-212		AOAC 6.2.02:2006 Official Method 991.47 Testing Disinfectants against Salmonella choleraesuis, Hard Surface Carrier Test Method.	Relevant guidance.
14-213		AOAC 6.2.03:2006 Official Method 991.48 Testing Disinfectants against Staphylococcus aureus, Hard Surface Carrier Test Method.	Relevant guidance.
14-215		AOAC 6.2.05:2006 Official Method 991.49 Testing Disinfectants against Pseudomonas aeruginosa, Hard Surface Carrier Test Method.	Relevant guidance.
14-216	14-363	AOAC 6.2.06:2012 Official Method 964.02 Testing Disinfectants against Pseudomonas aeruginosa, Use-Dilution Method.	Withdrawn and replaced with newer version.
14-217		AOAC 6.3.02:2006 Official Method 955.17 Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes.	Relevant guidance.
14-218		AOAC 6.3.05:2006 Official Method 966.04 Sporicidal Activity of Disinfectants Method I.	Relevant guidance.
14-225	14-364	ANSI/AAMI/ISO 11137-2:2012 Sterilization of health care products--Radiation--Part 2: Establishing the sterilization dose.	Withdrawn and replaced with newer version.
14-229		ASTM F1980-07 (Reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.	Relevant guidance.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
14-235		ASTM F1140-07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.	Relevant guidance.
14-236		ASTM F2054-07 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates.	Relevant guidance.
14-238		ANSI/AAMI/ISO 11140-5:2007/(R)2012 Sterilization of health care products--Chemical indicators--Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.	Reaffirmation.
14-256		ASTM F2095-07e1 Standard Test Methods for Pressure Decay Leak Test for Flexible Packages With and Without Restraining Plates.	Relevant guidance and editorial change.
14-257		ASTM D3078-02 (Reapproved 2008)$^{\epsilon 1}$ Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission.	Relevant guidance and editorial change.
14-278		ANSI/AAMI/ISO 10993-7:2008(R)2012 Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals.	Reaffirmation.
14-282		ASTM F2338-09 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method.	Relevant guidance.
14-283		ASTM F88/F88M-09 Standard Test Method for Seal Strength of Flexible Barrier Materials.	Relevant guidance.
14-288		ASTM F1886/F1886M-09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection.	Relevant guidance.
14-296		ANSI/AAMI/ISO 11138-1:2006/(R)2010 Sterilization of health care products--Biological indicators--Part 1: General requirements.	Relevant guidance, extent of recognition and title.
14-299		ASTM F2097-10 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products.	Relevant guidance.
14-300		ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems.	Relevant guidance.
14-313		ASTM F2475-11 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials.	Relevant guidance.
14-315	14-366	USP 35-NF30:2012 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14-316	14-367	USP 35-NF30:2012 <71> Sterility Tests.	Withdrawn and replaced with newer version.
14-317	14-368	USP 35-NF30:2012 <85> Bacterial Endotoxins Test.	Withdrawn and replaced with newer version.
14-318	14-369	USP 35-NF30:2012 <151> Pyrogen Test (USP Rabbit Test).	Withdrawn and replaced with newer version.
14-319	14-370	USP 35-NF30:2012 <161> Transfusion and Infusion Assemblies and Similar Medical Devices.	Withdrawn and replaced with newer version.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
14-320	14-371	USP 35-NF30:2012 Biological Indicator for Steam Sterilization, Self-Contained.	Withdrawn and replaced with newer version.
14-321	14-372	USP 35-NF30:2012 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14-322	14-373	USP 35-NF30:2012 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14-323	14-374	USP 35-NF30:2012 Biological Indicator for Steam Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14-324	14-375	USP 35-NF30:2012 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14-329	14-365	ISO 11137-2 Second edition 2012-03-15 Sterilization of health care products--Radiation--Part 2: Establishing the sterilization dose.	Withdrawn and replaced with newer version.
14-335		ISO 10993-7 Second edition 2008-10-15 Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals.	Extent of recognition and relevant guidance.
14-338		ISO 11138-1 Second edition 2006-07-01 Sterilization of health care products--Biological indicators--Part 1: General requirements.	Relevant guidance and extent of recognition.
14-345		ISO/ASTM 51261 First edition 2002-03-15 Guide for selection and calibration of dosimetry systems for radiation processing.	Relevant guidance.
14-359		ASTM F2096-11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test).	Relevant guidance.
14-360		ANSI/AAMI ST72:2011 Bacterial endotoxins--Test methods, routine monitoring, and alternatives to batch testing.	Relevant guidance.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 030.

Table 3.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Cardiovascular		
3-106	Medical electrical equipment--Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.	ANSI/AAMI/IEC 60601-2-25:2011.
3-107	Medical electrical equipment--Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	IEC 80601-2-30 Edition 1.0 2009-01.
3-108	Medical electrical equipment--Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers CORRIGENDUM 1.	IEC 80601-2-30 (First edition--2009).
3-109	Active implantable medical devices--Four-pole connector system for implantable cardiac rhythm management devices--Dimensional and test requirements.	ANSI/AAMI/ISO 27186:2010.
3-110	Active implantable medical devices--Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators.	AAMI TIR41:2011.
3-111	Cardiovascular implants--Endovascular devices--Part 3: Vena cava filters.	ANSI/AAMI/ISO 25539-3: 2011.
3-112	Cardiovascular implants and artificial organs--Blood-gas exchangers (oxygenators).	ANSI/AAMI/ISO 7199: 2009.
3-113	Cardiovascular implants and artificial organs--Blood-gas exchangers (oxygenators).	ISO 7199 Second edition 2009-04-15.
B. Dental/ENT		
4-200	Dentistry--Mercury and alloys for dental amalgam AMENDMENT 1: Requirements for marking and manufacturer's instructions concerning mercury.	ISO 24234 First edition 2004-10-15 AMENDMENT 1 2011-08-15.
C. General		
5-74	Medical electrical equipment--Part 1: General requirements for basic safety and essential performance, Amendment 1.	ANSI/AAMI ES60601-1:2005/C1:2009/(R)2012.
D. General Hospital/General Plastic Surgery		
6-292	Sterile hypodermic syringes for single use--Part 1: Syringes for manual use.	ISO 7886-1:1993 TECHNICAL CORRIGENDUM 1 Published 1995-11-01.
6-293	Sharps injury protection--Requirements and test methods--Sharps containers.	ISO 23907 First edition 2012-09-01.
E. In Vitro Diagnostics		
7-234	Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline--Second Edition.	CLSI EP24-A2.
7-235	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.	CLSI EP25-A.
7-236	Methods for Antimicrobial Susceptibility Testing for Human Mycoplasmas; Approved Guideline.	CLSI M43-A.
7-237	Molecular Methods for Clinical Genetics and Oncology Testing; Approved Guideline--Third Edition.	CLSI MM01-A3.
7-238	Quantitative Molecular Methods for Infectious Diseases; Approved Guideline--Second Edition.	CLSI MM06-A2.
7-239	Metrological Traceability and Its Implementation; A Report.	CLSI X5-R.

Table 3.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
F. Materials		
8-333	Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications.	ASTM F2393-12.
8-334	Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis.	ASTM F2459-12.
G. OB-GYN/Gastroenterology		
9-79	Water treatment equipment for haemodialysis applications and related therapies.	ISO 26722 First edition 2009-04-15.
9-80	Medical electrical equipment--Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.	IEC 60601-2-16 Edition 4.0 2012-03.
9-81	Mechanical contraceptives--Reusable natural and silicone rubber contraceptive diaphragms--Requirements and tests.	ISO 8009 First edition 2004-10-01 ISO 8009: 2004/Amd. 1: 2012 (E) AMENDMENT 1 2012-02-15
H. Ophthalmic		
10-75	Ophthalmic implants--Intraocular lenses--Part 7: Clinical investigations AMENDMENT 1.	ISO 11979-7 Second edition 2006-05-01 AMENDMENT 1 2012-01-15.
10-76	Ophthalmic implants--Intraocular lenses--Part 8: Fundamental requirements AMENDMENT 1.	ISO 11979-8 Second edition 2006-07-01 AMENDMENT 1 2011-05-15.
I. Orthopedic		
11-247	Standard Guide for Mechanical and Functional Characterization of Nucleus Devices.	ASTM F2789-10.
11-250	Implants for surgery--Wear of total hip joint prostheses--Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test.	ISO 14242-3 First edition 2009-03-15.
11-249	Implants for surgery--Wear of total hip joint prostheses--Part 2: Methods of measurement.	ISO 14242-2 First edition 2000-09-15.
11-248	Implants for surgery--Wear of total hip joint prostheses--Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test.	ISO 14242-1 Second edition 2012-01-15.
11-251	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.	ASTM F2554-10.
J. Radiology		
12-250	Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography CORRIGENDUM 1.	IEC 60601-2-44 (Third edition-2009).
12-251	Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography.	IEC 60601-2-44 Edition 3.0 2012-08 Amendment 1.

Table 3.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
K. Software/Informatics		
13-33	Validation of software for regulated processes.	AAMI TIR362007.
13-34	Medical device software--Part 1: Guidance on the application of ISO 14971 to medical device software.	IEC/TR 80002-1 Edition 1.0 2009-09.
13-35	Application of quality management system concepts to medical device data systems.	ANSI/AAMI SW87 2012.
13-36	Guidance on the use of AGILE practices in the development of medical device software.	AAMI TIR45 2012.
L. Sterility		
14-376	Sterilization of health care products--Moist heat--Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1.	ANSI/AAMI/ISO TIR 17665-2:2009.
14-377	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier.	ASTM F2638-12.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the Federal Register, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the Federal Register once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (See FOR FURTHER INFORMATION CONTACT). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address

of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the Federal Register, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 030" will be available on the CDRH home page. You may access the CDRH home page at http://www.fda.gov/MedicalDevices.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.

This Federal Register document on modifications in FDA's recognition of consensus standards is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see FOR FURTHER INFORMATION CONTACT) either electronic or written comments regarding this document. It

is only necessary to send one set of comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 030. These modifications to the list or recognized standards are effective upon publication of this notice in the Federal Register.

Dated: January 9, 2013.
Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013-00605 Filed 01/14/2013 at 8:45 am; Publication Date: 01/15/2013]